SUBSTITUTE FOR

HOUSE BILL NO. 4358

A bill to amend 1956 PA 218, entitled

"The insurance code of 1956,"

(MCL 500.100 to 500.8302) by adding section 3406v.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 3406v. (1) An insurer that delivers, issues for delivery, or renews in this state a qualified health plan that provides prescription drug coverage shall not do either of the following:

(a) Subject to subsection (2), remove a covered prescription drug from its list of prescription drugs or add utilization management restrictions to a formulary unless any of the following apply:

(*i*) The United States Food and Drug Administration has done any of the following:

(A) Issued a statement that calls into question the clinical safety of the drug.

(B) Required the manufacturers to conduct postmarket safety studies and clinical trials after the approval of the drug.

(C) Issued any drug safety-related labeling changes.

(D) Required the manufacturers to implement special risk management programs.

(*ii*) The manufacturer of the drug has notified the Secretary of the United States Department of Health and Human Services of a manufacturing discontinuance or potential discontinuance of the drug under 21 USC 356c.

(*iii*) The drug has changed from prescription to over-the-counter.

(*iv*) The change is intended to reduce preventable drug harm caused by inappropriate use, such as unintentional overdose or inappropriate prescribing.

(*v*) The change is based on clinically accepted medical best practices.

(*vi*) The change is a result of a newly approved drug with clinical advantage over existing drugs.

(*vii*) The price of the drug has increased by at least 10% over the price of the drug in the immediately preceding plan year.

(*viii*) The price of the drug has increased by at least 20% over the price of the drug in the plan year 3 years before the current plan year.

(*ix*) The drug is being added to the formulary.

(*x*) The drug receives a new United States Food and Drug Administration approval and has become available.

(*xi*) A generic equivalent or biosimilar alternative of the drug

has received United States Food and Drug Administration approval.

(*xii*) The insurer notifies the insured affected by the change in writing 90 days before the drug is removed from the formulary. For purposes of this subparagraph, the notice may be by electronic communication. The notice must include the telephone number of the insurer or the appropriate contractor or subcontractor for the insured to call for information regarding alternative therapeutically equivalent medication options.

(*xiii*) The insurer uses a pharmacy and therapeutics committee and the committee approves the change.

(*xiv*) The insurer grandfathers insureds on the affected drug to maintain coverage with current cost-sharing, deductible, copayment, or coinsurance for the remainder of the plan year.

(b) Subject to subsection (3), reclassify a drug to a more restrictive drug tier or move a drug to a higher cost-sharing tier or a tier with a larger deductible, copayment, or coinsurance, unless any of the following apply:

(*i*) The United States Food and Drug Administration has done any of the following:

(A) Issued a statement that calls into question the clinical safety of the drug.

(B) Required the manufacturers to conduct postmarket safety studies and clinical trials after the approval of the drug.

(C) Issued any drug safety-related labeling changes.

(D) Required the manufacturers to implement special risk management programs.

(*ii*) The change is based on clinically accepted medical best practices.

(*iii*) The change is a result of a newly approved drug with

clinical advantage over existing drugs.

(*iv*) A generic equivalent or biosimilar alternative of the drug has received United States Food and Drug Administration approval and has become available.

(*v*) The change is intended to reduce preventable drug harm caused by inappropriate use, such as unintentional overdose or inappropriate prescribing.

(*vi*) The drug has changed from prescription to over-the-counter.

(*vii*) The drug receives a new United States Food and Drug Administration indication.

(*viii*) The insurer uses a pharmacy and therapeutics committee and the committee approves the change.

(*ix*) The insurer grandfathers insureds on the affected drug to maintain coverage with current cost-sharing, deductible, copayment, or coinsurance for the remainder of the plan year.

(*x*) The insured affected by the change is notified in writing 90 days before the drug is removed from the formulary. For purposes of this subparagraph, the notice may be by electronic communication.

(*xi*) The price of the drug has increased by at least 10% over the price of the drug in the immediately preceding plan year.

(*xii*) The price of the drug has increased by at least 20% over the price of the drug in the plan year 3 years before the current plan year.

(2) During a qualified health plan year, if an insurer described in subsection (1) removes a covered prescription drug from its list of prescription drugs or adds utilization management restrictions to a formulary as allowed under subsection (1)(a), and

if an insured or enrollee's health care prescriber determines that the drug is medically necessary, for that insured or enrollee, the insurer shall treat the drug that is removed or for which restrictions are added under subsection (1)(a) as if the drug was not removed or the restrictions were not added.

(3) During a qualified health plan year, if an insurer described in subsection (1) reclassifies a drug to a more restrictive drug tier or moves a drug to a higher cost-sharing tier or a tier with a larger deductible, copayment, or coinsurance as allowed under subsection (1)(b), and if an insured or enrollee's health care prescriber determines that the drug is medically necessary, for that insured or enrollee, the insurer shall treat the drug that is reclassified or moved under subsection (1)(b) as if the drug was not reclassified or moved.

(4) This section does not prohibit the addition of prescription drugs to a qualified health plan's list of covered drugs during the plan year. This section does not impact or limit a generic or biosimilar substitution.

(5) This section does not prohibit an insurer described in subsection (1), by contract, written policy or procedure, or any other agreement or course of conduct, from requiring a pharmacist to effect generic substitutions of prescription drugs consistent with part 177 of the public health code, 1978 PA 368, MCL 333.17701 to 333.17780, under which a pharmacist may do either of the following:

(a) Substitute an interchangeable biological drug product for a prescribed biological drug product.

(b) Select a generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration.

(6) This section applies throughout the benefit period, from the beginning of the qualified health plan's deductible year until the end of the deductible year.

(7) If a provision of this section conflicts with a federal law, the federal law prevails.

(8) As used in this section:

(a) "Biological drug product" means that term as defined in section 17702 of the public health code, 1978 PA 368, MCL 333.17702.

(b) "Interchangeable biological drug product" means that term as defined in section 17704 of the public health code, 1978 PA 368, MCL 333.17704.

(c) "Qualified health plan" means that term as defined in section 1261.